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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,773

02/10/2004

Aya Jakobovits

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AGENSYS C/O MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/776,773	Applicant(s) JAKOBOVITS ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 14, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 14, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :05/06/05;
03/15/06; 04/05/06; 07/07/06; .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (claims 11-14, 16 and 39, SEQ ID NO: 6) in the reply filed on February 9, 2007 is acknowledged.

The Examiner concurs with Applicants' assessment of the Examiner's communication mailed January 23, 2007. The requirement mailed October 4, 2006 did not request a further election of one sequence from Figure 2. The Examiner's was flawed. The Examiner will examine all three sequences, SEQ ID NO: 6, 8 and 10 listed in independent claim 11.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 11, 14, 59 and 60 are pending.
Claims 1-10, 12, 13 and 15-58 have been cancelled.
Claims 11 and 14 have been amended.
Claims 59 and 60 have been added.
Claims 11, 14, 59 and 60 are examined on the merits.

Priority

3. The Examiner has reviewed the U.S. applications and provisional applications in which Applicants believe they derive benefit. Applicants' claims 11, 14, 59 and 60 encompass several polynucleotides and polypeptides that are not of record in their entirety in these six applications. Consequently, Applicants' are afforded the priority

Art Unit: 1643

date of the instant application, February 10, 2004. Applicants are invited to provide evidence substantiating the sequences in their entirety in any of the applications. One claim is afforded one priority date, which represents the date at which all limitations are disclosed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have added new claim 59, which recites "...the polypeptide sequence shown in SEQ ID NO:...35". Applicants assert support for this amendment can be found for example in figures 18 and 19, see Remarks submitted February 9, 2007, 1st paragraph of page 3. The Examiner has made a cursory review of the specification including the designated Figures and does not note SEQ ID NO: 35 as a polypeptide and suggested by the claim, but rather a nested oligonucleotide primer, see page 69 of the specification. The specification does not seem to have support of Applicants' contemplation of SEQ ID NO: 35 as a polypeptide. Applicants should pointedly

Art Unit: 1643

express where in the specification support can be found for this limitation or delete the new matter.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 59 suggests SEQ ID NO: 35 is a polypeptide sequence. However, it is a polynucleotide sequence consisting of 20 nucleic acid residues. Applicants should delete the sequence from the claim and/or present a claim that clearly denotes SEQ ID NO: 35 as a polynucleotide.

b. Claim 60 is vague and indefinite in the recitation, "...the polynucleotide is contained within a recombinant expression." It is not clear if the recitations such as "vector", "plasmid", "host cell" or "system" should follow the term "expression". Applicants should clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 1643

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 11, 14, 59 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2006/0003323 A1 (filed June 3, 2003). The publication discloses nucleic acid sequence 565, a NOVX nucleic acid fully complementary to the polynucleotide of claim 11, section b. This sequence comprises Applicants' nucleotide residue numbers 23 through 1210 of SEQ ID NO: 8, see SCORE mpbm database, result 8. The publication also discloses the anticipatory polynucleotide is contained within a recombinant expression vector, page 21, section 0095; and page 35, sections 0227, 0028 and 0230. It is readily envisaged that the anticipatory polynucleotide, which is the same as Applicants' SEQ ID NO: 8 encodes the polypeptide identified as SEQ ID NO: 9.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

01 April 2007